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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,701	09/30/1999	GEORGE H. LOWELL	406462000200	8314

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/214,701	LOWELL ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-24 and 26-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ ~~Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)~~ Paper No(s)/Mail Date *06172004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communications filed 08 and 29 January, 2002, and 17 June, 2004. Claims 1-18 and 25 were canceled without prejudice or disclaimer. Claims 19-24 and 26-32 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement filed 17 June, 2004, has been placed in the application file and the information referred to therein has been considered.

37 C.F.R. § 1.84

The drawings filed 17 June, 2004, in this application are not objected to under 37 C.F.R. § 1.84 or 1.152 and are deemed appropriate.

35 U.S.C. § 112, Second Paragraph

Claims 19-24, 26-29, and 31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims appear to be directed toward the generation of a mucosal immune response but do not specify any particular route of administration. Thus, it is not readily manifest if applicants intend to administer the vaccine composition to non-mucosal sites (which most likely would not produce the desired mucosal immune response) or mucosal sites. Appropriate correction is required. It is suggested that applicants amend the claim language to specify that the vaccine composition is administered via a mucosal route (i.e., intranasal administration).

Claim 26 further recites a step involving the "bonding" of a hydrophobic material to a protein which is vague and indefinite since it is not readily manifest what type of chemical reaction is encompassed by the claim language. Appropriate correction is required. It is suggested that applicants amend the claim language to specify that the hydrophobic foot is conjugated covalently to the NH_2-terminus of the protein.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 19 and 30-32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lowell (1998). Applicants traverse and submit that this teaching fails to provide a neutralizing mucosal antibody response. This argument is clearly untenable in view of the teachings set forth in columns 19 and 20. This portion of the patent describes the intranasal administration of a bacterial antigen comprising an endogenous hydrophobic sequence to a subject. It was reported (see col. 19, lines 10-12) that in "mice **anti-SEB respiratory IgA** and serum IgG were induced when the complexed compositions in saline were administered **intranasally**." The authors further added (bridging paragraph, cols. 19 and 20) that "Mice immunized **intranasally** with **proteosome-toxoid vaccines** were **significantly protected** ($p<0.0117$) against systemic challenge with

>4 LD100 of SEB". Thus, this teaching clearly meets all of the claimed limitations.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 22-24, 26, and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lowell (1998). Lowell (1998) describes the intranasal administration of a bacterial antigen comprising an

endogenous hydrophobic sequence to a subject. It was reported (see col. 19, lines 10-12) that in "mice anti-SEB respiratory IgA and serum IgG were induced when the complexed compositions in saline were administered intranasally." The authors further added (bridging paragraph, cols. 19 and 20) that "Mice immunized intranasally with proteosome-toxoid vaccines were significantly protected ($p<0.0117$) against systemic challenge with >4 LD100 of SEB". The inventor also describes the preparation of gp160 vaccine compositions (see cols. 17 and 18, "gp160 Vaccine Against AIDS"). This teaching does not disclose the generation of mucosal neutralizing antibody responses to a modified gp160. However, this teaching clearly illustrates that vaccine compositions carrying high molecular weight proteins with endogenous hydrophobic sequences, when combined with a proteosome formulation and administered intranasally, are capable of inducing strong neutralizing mucosal antibody responses. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to immunize a host with the gp160/proteosome composition taught by Lowell (1998) to induce a strong neutralizing mucosal antibody response, since this teaching clearly illustrates that proteosomes act as strong mucosal adjuvants.

Claims 20, 21, 27-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lowell (1998). This teaching discloses the preparation of proteosomal compositions comprising both high-molecular weight proteins with an endogenous hydrophobic sequence, as well as, polypeptides covalently conjugated to an exogenous hydrophobic material comprising between 3 and 5 non-polar amino acids. This teaching does not disclose that the proteosomal compositions comprising the polypeptide conjugates were capable of

inducing a neutralizing mucosal antibody response. However, Lowell (1998) clearly teaches that proteosomes are capable of inducing neutralizing mucosal immune responses against high-molecular weight immunogens. Lowell also teaches that the combination of polypeptides, hydrophobic feet, and proteosomes induces strong immune responses. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to immunize a host with the polypeptide/hydrophobic foot/proteosome composition taught by Lowell (1998) to induce a strong neutralizing mucosal antibody response, since this teaching clearly illustrates that hydrophobic feet/proteosomes act as strong mucosal adjuvants.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

20 August, 2005